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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Veronica Bordoni

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EXAMINER

KOSAR, AARON J

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,194	Applicant(s) BORDONI ET AL.	
	Examiner AARON J. KOSAR	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34-38,40,42-44 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group C (claims 53-59) in the reply filed on May 26, 2009 is acknowledged. The traversal is on the ground(s) that the Aiuti teaches cells co-cultured with Met-Murine Hepatocytes (MMH). This is not found persuasive because for the reasons of record, while Aiuti teaches co-culturing, Aiuti also teaches replacing half of the media wherein this replaced media (spent media), is effectively conditioned by the MMH cells and also freed from the MMH cells (replaced/removed from the other half of the media containing MMH cells).

Applicant's election without traverse of the species A (stem cell) in the reply filed on May 26, 2009 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31, 34-38, 40, 42-44, and 60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 26, 2009.

Claims 56-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 26, 2009.

Response to Amendment

Applicant's amendments and arguments filed on October 23, 2008 and May 26, 2009 in reply to the non-final rejection are acknowledged and have been fully considered.

Applicant has amended the claims by canceling claims 32, 33, 39, 41, and 45-52. Claims 31, 34-38, 40, 42-44, and 53-60 are pending of which claims 31, 34-38, 40, 42-44, and 56-60 are withdrawn.

Claims 53-55 are pending and have been examined on their merits.

Claim Objections

Claim 53 is objected to because of the following informalities: The phrase "by MMH cells (c-Met Transgenic Murine Hepatocyte)" in claim 53, lines 3-4, should recite the expanded term followed by the abbreviation, as follows: -- by c-Met Transgenic Murine Hepatocyte (MMH) cells --

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Response to Arguments

Applicant has argued that the organism is known and readily available (Remarks 10/23/2008, page 9, paragraph 2) and thus enabled under 35 USC 112, ¶1 and that the organism is "available upon request".

Applicant's arguments have been fully considered; however, they are found to be not persuasive, because the establishment of public-availability of the organism is unclear and the organism required to make and/or use the invention appears to have not meet all of the criteria set forth in 37 C.F.R. §§ 1.801-1.809.

In the instant case, Applicant has argued that the organism (mice) is/are “available upon request”, directed to an instant inventor, Tripodi; however, since the organism has not been deposited in a public depository existing independent of the control of the inventors, it is unclear if the organism(s) will remain available to the public beyond the effective life of the patent. The availability is unclear because Applicant has not provided assurance that (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request; that (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent; and that (iii) the organism(s) will remain available to the public during and/or beyond the effective life of the patent. Also MPEP § 2404.01 states,

If an Applicant has adequately established that a biological material is known and readily available, the Office will accept that showing. In those instances, however, the Applicant takes the risk that the material may cease to be known and readily available. Such a defect cannot be cured by reissue after the grant of a patent.

Also, once Applicant has established that the material is known and readily available, any information to the contrary which comes to an Applicant's attention during the prosecution of this application, must be entered in the record or otherwise be brought to the attention of the Office by the Applicant.

Claims 53-55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological materials, including MMH cell lines used in the invention and/or the transgenic organism(s) from which the cells/cell lines are obtained. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials, and it is not apparent if the biological materials are readily available to the public. It is unclear if Applicant has deposited the biological materials and there is no indication in the specification as to public availability.

If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide

Art Unit: 1651

assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit must be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §1.807) and
- (e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information; however, Applicant is cautioned to avoid entry of new matter into the specification by adding any other information.

Finally, Applicant is advised that the address for the ATCC has recently changed, and that if deposited with the ATCC repository, the new address should appear in the specification. The new address is: *American Type Culture Collection, 10801 University Boulevard, Manassas, VA, 20110-2209.* (See also MPEP §2405, 37 CFR §1.803)

Art Unit: 1651

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites “free from conditioning cells” in line 4; however it is unclear if the cells are the MMH cells or if other cells are intended. Clarification is required.

Claim 53 recites “mammalian cells”, “conditioning cells” and “MMH cells”; however, it is unclear if the cells are the same cells or different cells. Clarification is required.

Because claims 54 and 55 depend from indefinite claim 53 and do not clarify the point of confusion and/or are deficient for the same reasons as claim 53, they must also be rejected under 35 U.S.C. 112, second paragraph.

Allowable Subject Matter

The following claim would likely be distinguished over the art of record in this application (and with sufficient showing of public availability as argued elsewhere in this communication), and is presented to Applicant for consideration:

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53. A method for growing, expanding, and/or maintaining isolated mammalian cells *in vitro*, the method comprising:

- (a) conditioning a culture medium with c-Met Transgenic Murine Hepatocyte (MMH) cells;
- (b) removing or separating the MMH cells therefrom to provide an MMH cell-free conditioned culture medium;
- (c) contacting a mammalian cell with the conditioned culture medium obtained from step (b); and
- (d) culturing the mammalian cell in the conditioned culture medium for a period of time sufficient to grow, expand, and/or maintain the mammalian cells in the contacted culture medium,

wherein the cultured mammalian cells are selected from the group consisting of bone marrow cells, cord-blood stem cells, non-human embryonal stem cells, adult stem cells, endodermal cells, ectodermal cells, mesodermal cells, natural killer (NK) cells, dendritic cells, and endothelial cells.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Christopher R. Tate/
Primary Examiner, Art Unit 1655